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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,043

03/17/2008

David Gaudout

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12/18/2009

WIGGIN AND DANA LLP
ATTENTION: PATENT DOCKETING
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EXAMINER

PIHONAK, SARAH

ART UNIT

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1627

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,043	Applicant(s) GAUDOUT ET AL.	
	Examiner SARAH PIHONAK	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application, filed on 3/17/2008, is a national stage entry of PCT/FR04/03173, filed on 12/9/2004.

Priority

This application claims foreign priority to Application No. 0314394, filed on 12/9/2003.

Response to Remarks

1. Applicant's arguments filed 8/31/2009 have been fully considered but they are not persuasive. However, in further consideration of the claims, a new art rejection has been made, which will be discussed in detail further in this office action. Accordingly, this action is made NON-FINAL.

Claims 1-3 and 7-10 have been cancelled by the Applicants. Claims 4-6, and 11-19 are pending.

2. Claims 4-6 and 11-19 were examined.

3. Claims 4-6 and 11-19 are rejected.

Claim Rejections-35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Gara et. al., *Applied & Environmental Microbiology*, 66 (5), pp. 2269-2273, (2000), in view of Hsu et. al. EP Patent Application No. 945066.

8. The claims are drawn to a composition containing diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl tetrasulfide, the sum by weight of which is at least 1 mg. per gram of composition, and includes formulation adjuvants.

O'Gara et. al. teaches that garlic oil, which is prepared by heating crushed garlic cloves followed by distillation, contains diallyl sulfide, diallyl disulfide, diallyl trisulfide,

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and diallyl tetrasulfide (p. 2269, right column, first full paragraph; p. 2270, right column, Table 1). The amount of diallyl sulfide present is taught as being 106 mg/g of garlic oil; the amount of diallyl disulfide is 530 mg/g of garlic oil; the amount of diallyl trisulfide is 115 mg/g of garlic oil; and the amount of diallyl tetrasulfide is 43 mg/g of garlic oil (p. 2270, right column, Table 1), which meets the limitation that the sum of diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl tetrasulfide is at least 1 mg/g. of the composition. It is taught that diallyl disulfide comprises 53 % of the weight of garlic oil; diallyl trisulfide comprises 11.5 % of the weight of garlic oil; and diallyl tetrasulfide comprises 4.3 % of the weight of garlic oil (p. 2270, right column, Table 1); therefore, at least 50 % of the diallyl polysulfides consist of diallyl disulfide and diallyl trisulfide.

O'Gara et. al. teaches that the garlic oil is normally diluted 200:1 with a vegetable oil, to reflect the level of allicin in freshly crushed garlic (p. 2269, right column, first full paragraph). While at this dilution, the amount of diallyl disulfide, diallyl trisulfide, diallyl tetrasulfide, and diallyl sulfide would be less than 1 mg/g. of composition, it would have been considered routine and obvious to one of ordinary skill in the art to reduce the dilution factor or to optimize the amount of diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl tetrasulfide present to obtain a collective weight of diallyl sulfide, -disulfide, -trisulfide, and -tetrasulfide to at least 1 mg/g. of composition, for formulation enhancement and stability. Nevertheless, it is taught that concentrated garlic oil naturally contains a collective weight amount of diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl tetrasulfide which is considerably greater than 1 mg/g. of garlic oil.

O’Gara et. al. does not explicitly teach formulation adjuvants for biopesticide compositions, such as plant oil adjuvants.

Hsu et. al. teaches a natural pesticide composition comprised of extracts of garlic and adjuvants, such as essential oils, including cottonseed oil, cinnamon oil, along with other plant oils (Abstract; p. 2, paragraph [0005]). Hsu et. al. teaches that garlic extract includes garlic oil (p. 2, paragraph [0007]). Hsu et. al. teaches that the pesticide comprised of the garlic extract and essential oils is effective against fungal infestations of plants and also possesses anti-bacterial properties (p. 2, paragraph [0003]). Additionally, Hsu et. al. also teaches that the composition comprised of the garlic extract and plant oils was diluted with water, which in some instances resulted in reduced effectiveness of the formulation as a pesticide (p. 4, paragraphs [0023-0024]).

It would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to add an adjuvant such as cottonseed oil, cinnamon oil, or another plant oil to the garlic oil taught by O’Gara et. al., because Hsu et. al. teaches that a composition comprised of garlic extracts (including garlic oil) and essential oils is an effective pesticide and bactericide. Furthermore, as Hsu et. al. teaches that too great a dilution factor of the garlic extract results in reduced effectiveness of the composition as a pesticide, one of ordinary skill in the art would have been motivated to optimize the concentration of the sulfur compounds in the garlic extract to increase the potency as a pesticide and biocide. As O’Gara et. al. teaches that undiluted garlic oil contains diallyl polysulfides in an amount significantly greater than 1 mg/g. of garlic oil, it would have been considered obvious for one of ordinary skill in the art to optimize the activity of the

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garlic extract composition as a pesticide while enhancing stability, and formulate the composition so that the amounts of diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl tetrasulfide are collectively at least 1 mg/g. of the composition.

Claim Rejections-35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Gara et. al., *Applied & Environmental Microbiology*, **66 (5)**, pp. 2269-2273, (2000), in view of Hsu et. al. EP Patent Application No. 945066, as applied to claims 4-6 above, and further in view of Lawson et. al., *J. Natural Products*, **54 (2)**, pp. 436-444, (1991), and Yeh et. al., *The Journal of Nutrition*, **131 (3S)**, pp. S989-S993, (2001), Block et. al., *Pure & Applied Chem.*, **65 (4)**, pp. 625-632, (1993), and Yu et. al., *J. Agric. Food Chem.*, **37**, pp. 725-730, (1989).

13. The claims are drawn to a composition containing diallyl sulfide, diallyl disulfide, diallyl trisulfide, diallyl tetrasulfide, the sum by weight of which is at least 1 mg/g of composition, and gamma-glutamyl-S-allylcysteine (Gluacs). Atleast 50% of the diallyl polysulfides consists of diallyl disulfide and diallyl trisulfide. The composition comprises an extract of garlic, and contains diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, allicin, and allicin. The compounds diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, and allicin are predominant in the extract of garlic, and the diallyl polysulfides represent more than 50 % of the sulfur-containing compounds of the garlic extract.

O'Gara et. al. teaches that garlic oil, extracted from garlic cloves, comprises diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl trisulfide, the sum of which is

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greater than 1 mg/g. of garlic oil. Hsu et. al. teaches that a composition comprised of garlic extracts and adjuvants such as plant oils is an effective pesticide and biocide. Additionally, O'Gara et. al. teaches that garlic oil comprises methyl allyl polysulfides, such as methyl allyl disulfide, methyl allyl trisulfide, methyl allyl tetrasulfide, methyl allyl pentasulfide, and methyl allyl hexasulfide (p. 2270, right column, Table 1). The diallyl polysulfides of garlic oil comprise more than 50 % of the sulfur-containing compounds present in garlic oil (p. 2270, right column, Table 1). O'Gara et. al. also teaches that garlic oil further comprises dimethyl polysulfides, such as dimethyl tri-, tetra-, and pentasulfide (p. 2270, right column, Table 1), and that the compound, allicin, is formed by a catalytic process when garlic cloves are crushed (p. 2269, left column, last paragraph-right column, top paragraph). It is also taught that during the process of preparing garlic oil, or when crushed garlic cloves are heated and processed by distillation, allicin becomes converted to diallyl sulfides, diallyl polysulfides, and many other sulfide compounds observed in garlic oil and garlic extracts (p. 2269, right column, first full paragraph). O'Gara et. al. also teaches that the compound alliin is present in garlic, and during crushing of garlic cloves alliin reacts with the enzyme alliinase to form allicin (p. 2269, left column, last paragraph-right column, top paragraph). O'Gara et. al. teaches that the garlic oil is prepared by heating crushed cloves to 100 C, followed by distillation and collection of the distillate (p. 2269, right column, first full paragraph). This process is consistent with the claimed process of milling the garlic under hot conditions, and recovering the volatile fractions. Steps such as filtering the garlic and concentrating

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the distillate under vacuum would have been considered part of the distillation process to one of ordinary skill in the art.

O’Gara et. al. and Hsu et. al. do not explicitly teach that garlic extract contains gamma-glutamyl-S-allylcysteine, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, or dimethyl polysulfinate.

Lawson et. al. teaches that the compound gamma-glutamyl-S-allylcysteine is present in garlic extracts (Abstract; p. 436, first paragraph). Lawson et. al. teaches that this compound is observed in extracts prepared from homogenized garlic (p. 442, Table 1; p. 443, second full paragraph).

Yeh et. al. teaches that dipropyl polysulfides such as dipropyl disulfide and dipropyl trisulfide are naturally found in garlic, and contribute to the medicinal properties of garlic (Abstract; p. S992, left column, middle paragraph).

Block et. al. teaches that extracts of garlic naturally contain dimethyl thiosulfinate, among other thiosulfinate and sulfide containing compounds (Abstract; p. 630, Table I, 13th entry). Block et. al. teaches preparing the garlic extract by homogenizing garlic cloves, followed by vacuum distillation to recover the concentrated extracts (p. 628, lower paragraph-p. 629, top paragraph).

Yu et. al. teaches that the compounds that allyl propyl polysulfides, such as propyl allyl disulfide, is present in garlic and garlic extracts (Abstract; p. 729, Table II). Yu et. al. also teaches that the methyl propyl polysulfide, such as methyl propyl disulfide, is also present in garlic extracts (p. 729, Table 11). Yu et. al. teaches that the

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garlic extract is obtained by homogenizing the garlic cloves, followed by extraction and distillation) p. 726, right column, lower paragraph-p. 727, left column, top paragraph).

Collectively, O'Gara et. al., Yeh et. al., Lawson et. al., Block et. al., and Yu et. al. teach that diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, allicin, alliin, and gamma-glutamyl-S-allylcysteine are all naturally found in garlic, as they have been identified in garlic extracts. O'Gara et. al. also explicitly teaches that diallyl disulfide and diallyl trisulfide constitute more than 50 % of the diallyl polysulfide compounds observed in garlic extracts, and the diallyl polysulfides represent more than 50 % of the sulfur-containing compounds found in garlic extracts. Hsu et. al. teaches that a composition comprised of garlic extracts and plant oil adjuvants is a superior pesticide and biocide. Therefore, it would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to add a plant oil adjuvant to the garlic oil taught by O'Gara et. al., for formulation purposes, because it is known in the art the compositions comprised of garlic extracts (including garlic oil) is a potent pesticide and biocide. Additionally, the prior art teaches that diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, allicin, alliin, and gamma-glutamyl-S-allylcysteine are all naturally found in garlic extracts; therefore, these compounds would also have been present in a composition comprised of garlic extracts. As O'Gara et. al. teaches that undiluted garlic oil contains diallyl polysulfides in an amount significantly greater than 1 mg/g. of garlic oil, it would have been considered

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obvious for one of ordinary skill in the art to optimize the activity of the garlic extract composition as a pesticide while enhancing stability, and formulate the composition so that the amounts of diallyl sulfide, diallyl disulfide, diallyl trisulfide, and diallyl tetrasulfide are collectively at least 1 mg/g. of the composition.

Claim Rejections-35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. The claims are drawn to a composition in which the compounds diallyl polysulfides, allyl methyl polysulfides, dimethyl polysulfides, allyl propyl polysulfides, methyl propyl polysulfides, dipropyl polysulfides, dimethyl thiosulfinate, and allicin, are predominant in the extract of garlic. It is not certain what is meant by the term 'predominant', as a numerical value or a numerical range has not been stated for this term. Therefore, the limitations of the claims can not be determined, and the claims are rejected for being indefinite. However, for prior art purposes, the term 'predominant' was interpreted as meaning greater than 50 %.

Conclusion

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17. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-every other Friday 8:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1627